

# Handbook for Vaccine Supplied by the Division of Immunization

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UPDATED FORMS CAN BE ACCESSED ON  
OUR WEBSITE OR THROUGH YOUR VVFC CONSULTANT

# VVFC ENROLLMENT

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## **Overview**

The Virginia Department of Health (VDH), Division of Immunization (DOI) manages the Virginia Vaccines for Children's (VVFC) program. Through utilization of private and public providers, DOI and the VVFC program reduce barriers to immunizations for children and adults. DOI supplies federally and state purchased vaccine at no cost to public and private health care providers.

The national Vaccines for Children (VFC) program was established to help raise childhood immunization rates in the United States and to keep children in their medical home. The entitlement program is associated with each State's Medicaid plan. Children who are eligible for VFC vaccines are entitled to receive pediatric vaccines that are recommended by the Advisory Committee on Immunization Practices.

The VVFC program handles distribution of all vaccines provided by DOI, in addition to those for the VFC entitlement program. DOI, through relationships with public providers is able to serve populations in addition to VVFC eligible, such as children needing immunizations for school, and vaccines for adults who are underinsured or uninsured.

## **Program Benefits**

- ✓ Increased vaccination rates for otherwise unprotected children
- ✓ Decreased morbidity and mortality from vaccine-preventable diseases
- ✓ Increased herd immunity for your local community
- ✓ Reduce referrals to public clinics, allowing these patients to remain in their medical homes and ensuring continuity of care
- ✓ Save money on your vaccine purchases by receiving publicly purchased vaccines covered under the program
- ✓ Technical assistance to improve your vaccination rates, record keeping, vaccine handling, and vaccination opportunities

## **VVFC Enrollment Process**

To enroll in the Virginia Vaccines for Children Program, providers may call 1-800-568-1929 or 1-804-864-8055 to receive an Enrollment Packet or click on <http://www.vdh.virginia.gov/Epidemiology/Immunization/VFC/vfcEnroll.htm> to print an Enrollment/Registration Form. The **Enrollment/Registration Form** contains basic information about your facility and the number of patients receiving immunizations

annually. Medicaid HMO patients should be counted as “Medicaid”. FAMIS is low cost insurance, so FAMIS patients should be counted as “Insured.” A temperature log demonstrating adequate storage for vaccine must be submitted along with your initial Registration Form.

### **Practice Identification Number**

A Practice Identification Number (PIN) will be assigned to you when you enroll. Knowing the PIN assigned to your facility helps us to quickly and accurately find your records and answer your questions. Please contact the Order Center if there is a change in your medical facility such as: contact people, mailing addresses, shipping addresses, practice hours, email addresses, and physicians. This helps ensure you receive your vaccine products in a timely and efficient manner. Major changes in your facility may require a new PIN, re-classification, or a registration update. Please contact the VVFC Program if you have questions about your classification. PINs are assigned to a particular site and do not transfer with a physician or nurse.

### **Multiple Office Enrollments**

Depending on your organization, you may be assigned more than one PIN. If there is more than one facility under the same medical group (sharing staff and/or patients) and each facility is storing and administering vaccine provided through DOI, a parent PIN is assigned. The parent PIN is assigned to the medical group’s main location. A related PIN identifying all locations of associated with the medical group will be assigned to each location. For example, a parent PIN might be P999. All other locations would be distinguished with the PIN and a letter following the number, such as: P999-A, P999-B, and P999-C, etc. The provider profile section of each registration form should estimate the number of patients needing immunizations at each location. NOTE: Offices that do not order vaccine because vaccine is temporarily transferred for the day from another main office, do not need to register. If the location permanently stores vaccine, it should register as a separate site.

### **Facility Types**

The majority of providers enrolled in the VVFC program are private physician offices. Other enrolled facilities include Federally Qualified Health Centers (FQHCs), a Rural Health Clinics (RHCs), or a Community Health Centers (CHCs), Public Hospitals, and Local Health Departments.

### **Inactive Membership Status**

Contact the Order Center if your facility closes or no longer wants to participate in the VVFC program. We will assist you in transferring unused, viable, vaccines provided by DOI to a participating VVFC enrolled provider.

As a VVFC provider, you agree to adhere to federal and state program guidelines. If at any time your practice does not adhere to them, your facility’s enrollment may be inactivated.

# ELIGIBILITY

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*Eligibility Classifications*  
*Provider Classifications and their Funding Sources*  
*Out of State VVFC Eligible Children*  
*Medicaid Eligibility Reference*  
*Children Not Eligible VVFC Vaccine*  
*Screening Documentation*

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## **Eligibility Classifications**

A patient's eligibility for vaccine supplied through DOI depends on the facility type where the patient is being seen. A patient's eligibility may be either VFC eligible or State/\$317 eligible. Below are listed eligibility classifications for patients and the providers that serve them:

### **VFC ELIGIBLE ARE:**

Medicaid eligible (All ACIP recommended vaccines are available from all VFC Providers): A child through 18 years of age who is eligible for the Medicaid program. The terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent and refer to children who qualify for the state Medicaid entitlement program. Medicaid is an entitlement - not insurance. (FAMIS IS INSURANCE AND NOT VFC ELIGIBLE) Medicaid HMOs are: AMERIGROUP, Anthem Health Keepers Plus, CareNet, MajestaCare, Optima Family Care, and VA Premier.

Uninsured eligible (All ACIP recommended vaccines are available from all VFC Providers): A child through 18 years of age who has no health insurance coverage American Indian (AI) or Alaska Native (AN) (All ACIP recommended vaccines are available from all VFC Providers): A child through 18 years of age and AI/AN as defined by the Indian Health Care Improvement Act (25 U.S.C. 1603)

Underinsured (at Federally Qualified Health Centers (FQHCs) or Rural Health Clinics (RHCs): A child through 18 years of age who has commercial (private) health insurance but the coverage does not include vaccines, or a child whose insurance covers only selected vaccines, or a child whose insurance caps vaccine coverage at a certain amount (once that coverage amount is reached, the child is categorized as underinsured). Underinsured children are VFC eligible through a FQHC, or RHC. For example, an insured female under the age of 19, whose insurance does not cover HPV can be immunized with VFC funded vaccine supplied through DOI, at a FQHC or RHC.

### **STATE/\$317 ELIGIBLE ARE:**

Code Required Vaccine required for school entry are available at LHDs: Patients who are not eligible as Medicaid, Uninsured, AI/AN, Underinsured at FQHC/RCH (defined above), and are under the age of 19 may receive routine vaccines required for school entry at LHDs. For example, a child with insurance is eligible for DOI supplied vaccines required for school entry at a LHD but the child is not VFC eligible. Rather, the child is State/\$317 eligible as dictated by billing policies for health departments. The LHD may bill the insurance as directed by VDH billing policies for LHDs.

The vaccines required for school are:

DTaP

hepatitis B

Hib

MMR

pneumococcal conjugate

polio

Tdap

varicella and,

HPV vaccine may be administered free of charge to all females who will be enrolled in the 6th grade as well as all other females who are 11 or 12 years of age.

\*Hepatitis A, Meningococcal, and Rotavirus vaccines are ACIP recommended vaccines, but are not required for school entry. Only VVFC eligible (ie. Medicaid, Uninsured, AI/AN, Underinsured at FQHC/RCH) children qualify for DOI provided Hepatitis A, Meningococcal, Rotavirus and HPV vaccines. Insured patients should receive privately purchased Hepatitis A, Meningococcal, Rotavirus vaccine and HPV vaccine (if outside the guidelines for HPV above).

Underinsured Children (covered at a LHD/Public Hospital): All ACIP

recommended vaccines are available for underinsured children through 18 years of age. A child through 18 years of age who has commercial (private) health insurance but the coverage does not include vaccines, or a child whose insurance covers only selected vaccines, or a child whose insurance caps vaccine coverage at a certain amount (once that coverage amount is reached, the child is categorized as underinsured).

Adult Eligible (covered at a LHD/FQHC/RCH/Public Hospital): Influenza,

MMR, TD/Tdap, Meningococcal, Varicella, Zoster, HPV, Pneumococcal, Hepatitis B (through VAHBII Program), vaccines are available for patients 19 years of age and older who are uninsured, or underinsured. Underinsured is defined as: A person who has commercial (private) health insurance but the coverage does not include vaccines, or a person whose insurance covers only selected vaccines, or a person whose insurance caps vaccine coverage at a certain amount (once that coverage amount is reached, the person is categorized as underinsured).

### **Funding / Provider Classifications**

Vaccines are supplied by DOI at no cost to enrolled providers using three primary funding sources:

- VFC funds are used to purchase vaccine for VFC eligible children. VFC eligible children are Medicaid, Uninsured, AI/AN, and Underinsured at FQHC/RCH.
- Section 317 funds are used to purchase vaccines for underinsured clients and uninsured adult in LHDs, FQHCs, RHCs, and Public Hospitals, school based clinics, and for outbreak control.

- State funds are used to support code-required vaccine for non-VFC eligible patients in LHDs, and adult immunizations. (Refer to billing policies for local health departments.)

Section 317 and State funds supporting public providers expand the eligibility criteria in public settings as seen by the shaded portion of the table below. Use the table below to determine if a patient is eligible for vaccine provided by DOI. You need to know:

- 1) Type of provider seeing the patient (left column)
- 2) Does the patient meet at least one of the eligibility criteria for that setting?

<b>Provider Classification</b>	<b>Eligibility Classification</b>					<b>Adults &gt;18 years of age</b>
	<b>Children &lt;19 years of age</b>					
<b>(PIN Prefix)</b>	<b>Medicaid</b>	<b>Uninsured</b>	<b>AI/AN</b>	<b>Underinsured</b>	<b>Insured child/Code Required*</b>	<b>Uninsured &amp; Under-insured*</b>
<b>Private Physician (Ps)</b>	<b>VVFC Eligible</b>	<b>VVFC Eligible</b>	<b>VVFC Eligible</b>			
<b>Local Health Department (FIPS Code)</b>	<b>VVFC Eligible</b>	<b>VVFC Eligible</b>	<b>VVFC Eligible</b>	<b>(State/317) Eligible</b>	<b>(State/) Eligible</b>	<b>(State/317) Eligible</b>
<b>FQHC/RCH (Fs)</b>	<b>VVFC Eligible</b>	<b>VVFC Eligible</b>	<b>VVFC Eligible</b>	<b>VVFC Eligible</b>		<b>(State/317) Eligible</b>
<b>Public Hospital (As)</b>	<b>VVFC Eligible</b>	<b>VVFC Eligible</b>	<b>VVFC Eligible</b>	<b>(State/317) Eligible</b>		<b>(State/317) Eligible</b>

\*CDC changes for 317 funds and use of the federal contract affecting eligibility for children and adults

### **Out of State Eligible**

Patients should be vaccinated with vaccine supplied by the state in which the provider/facility is located. Facilities should include border state children (and adults at LHD, FQHC/RHC/Public Hospital) served by their practice in their profile estimates on the Registration Form. For children covered under Medicaid, bill the administration fee to the state providing the child's Medicaid coverage.

### **Medicaid**

- Department of Medical Assistance (DMAS) will reimburse \$11 for all shots administered to VFC eligible clients. DMAS will also reimburse for the appropriate office visit fee on the same date as the vaccination reimbursement. Reimbursement is paid per vaccine CPT code billed Ex: 90715 Tdap will reimburse at \$11 when the "shot" code is billed.
- DMAS will not reimburse the provider an administration fee for children or adults
- For Adults and non VFC eligible patients DMAS will reimburse for cost of vaccines (CPT codes) and an appropriate office visit fee if the vaccine is determined to be medically necessary. Documentation of medical necessity must be attached with the claim. Use privately purchased vaccine when requesting reimbursement. Note: It is fraudulent to request reimbursement for vaccine provided free of charge.

- DMAS will not reimburse for an administration fee using CPT 90460-461

[http://www.dmas.virginia.gov/Content\\_atchs/mc/mc-guide\\_p1.pdf](http://www.dmas.virginia.gov/Content_atchs/mc/mc-guide_p1.pdf)

### **Screening Documentation**

DOI provides federally and state purchased vaccine at no charge to providers for administration to eligible patients. To assure DOI supplied vaccine is administered to eligible patients, each patient should be screened at each patient visit. Screening forms at <http://www.vdh.virginia.gov/Epidemiology/Immunization/VFC/vfcForms.htm> may be used or you may create a similar form. The VVFC office must approve all alternative screening methods.

If your facility uses the Patient Eligibility Screening Record, the VVFC office recommends a second copy be kept as a complete record of the medical facility's eligible children. This consolidated file will assist your practice in annually updating the provider profile section of the Registration Form.

A Patient Eligibility Screening Record must be completed for each child and verified at each subsequent visit. If an eligible child becomes ineligible, the screening form should reflect the change and date of change. Patient Eligibility Screening Records must be kept in the patient's chart for three years.

If you use the VVFC Vaccine Administration and Screening Record, the child must still be screened for VVFC eligibility at each visit. Screening is recorded in a designated column of the administration record. This column allows for documentation at each vaccine administration and requires no additional paper if eligibility changes.

# CONTRACT

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## *VVFC Contract Terms* *Updating Your VVFC Contract*

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### **VVFC Contract Terms**

The signed Registration Form is a contractual agreement. The contractual section of the Registration Form states:

### **VFC Program Contract**

**To participate in the Virginia Vaccines For Children (VVFC) Program and receive federally and/or state procured vaccine provided to my facility at no cost, I, on behalf of myself and any and all practitioners associated with this medical office, group practice, Health Maintenance Organization, hospital, health department, community/migrant/rural clinic, or other entity of which I am the physician-in-chief or equivalent, agree to:**

- Screen all immunization encounters for eligibility. Administer VVFC federal and state-purchased vaccine to a) Federally vaccine-eligible children who are 18 years of age or younger and meet one or more of the following categories: i) enrolled in Medicaid ii) has no health insurance iii) is an American Indian or Alaskan Native iv) is underinsured: a person who has commercial (private) health insurance but the coverage does not include vaccines, persons whose insurance covers only selected vaccines (VFC- eligible for non-covered vaccines only), or children whose insurance caps vaccine coverage at a certain amount-- once that coverage amount is reached, these persons are categorized as underinsured. Underinsured children are eligible to receive VFC vaccine through a Federally Qualified Health Center (FQHC) or, Rural Health Clinic (RHC) b) State vaccine-eligible children 18 years of age or younger at LHD who are not eligible for federal VFC funded vaccine and are receiving immunizations required for school i) DTaP, hepatitis B, Hib, MMR, pneumococcal conjugate, polio, Tdap, and Varicella vaccines ii) HPV for females who are 11 or 12 years of age iv) c) State and 317 uninsured and underinsured adults 19 years of age and older at FQHC/RHC/LHD/Participating Public Hospital i) receiving ACIP recommended vaccine d) 317 underinsured children 18 years of age or younger at a Participating Public Hospital, or LHD i) receiving ACIP recommended vaccine.
- Maintain all records related to the VFC program for a period of 3 years, and make these records available to the State Health Department or the Department of Health and Human Services (DHHS). Release of records will be bound by the privacy protection of Federal Medicaid Law.
- Comply with the immunization schedules, dosage, and contraindications established by the DHHS Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:
  - In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate.
  - The particular requirements contradict state law, including those pertaining to religious and other exemptions.
- Provide the most current vaccine information statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act, which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
- Not impose a charge for the cost of the vaccine.
- Charge the vaccine administration fee charged to non-Medicaid VFC-eligible children cannot exceed \$14.71 per vaccine dose, the established fee set forth by the state.
- Accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans for Medicaid VFC-eligible children.



- Not deny administration of a federally procured vaccine to a child due to the inability of the child's parent/guardian/ individual of record to pay an administration fee.
- Comply with the State's requirements for vaccine ordering, vaccine accountability, and vaccine management. I agree to operate within the VVFC program in a manner intended to avoid fraud and abuse.

The State or provider may terminate this agreement at any time for personal reasons or failure to comply with these requirements. If the provider chooses to terminate the agreement, he or she agrees to properly return any unused VFC vaccine.

The VVFC program requires a main contact physician authorized to prescribe vaccines to sign this contract. In certain instances a Nurse Practitioner or Physician Assistant may sign if there is not a Physician in charge. All additional Physicians, Nurse Practitioners, and Physician Assistants that participate in the VVFC program at your facility must register by signing page 2 of the Registration Form.

### **Updating Your VVFC Contract**

VVFC providers shall register annually to update contact information and patient profile data.

You will be notified when it is time to update your registration. In order to maintain current enrollment status, your practice will have approximately 30 days to return the registration form to the VVFC office. If your practice does not comply by sending the necessary registration information, a hold will be placed on your facility's vaccine orders. To order vaccines again, you must submit a Registration Form. Please be sure to submit your annual registration update on time.

Although the registration is updated annually, please notify the Order Center of new contact people, mailing addresses, shipping addresses, practice hours, email addresses, and physicians as they occur. This helps ensure our data is current and that you receive your vaccine products in a timely and efficient manner.

# ORDER CENTER

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*Vaccine Availability*  
*How to Order Vaccines*  
*When to Order Vaccines*  
*Direct Ship Vaccine*  
*Missing or Incorrect Shipments*  
*Vaccine Holds*

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## **Vaccine Availability**

All ACIP recommended vaccines may be ordered through the Virginia Department of Health, Division of Immunization. The Centers for Disease Control and Prevention (CDC) negotiates vaccine contracts with manufacturers periodically. As a result, a particular brand of vaccine may not be available every time you order. When a particular brand of vaccine is not available, it may be due to constraints and limitations imposed by CDC or a vaccine manufacturer. If this occurs, the VVFC office will send your facility an alternate, interchangeable vaccine.

## **How to Order Vaccines**

The Vaccine Order Forms are periodically updated to reflect the latest changes in vaccine availability. The most current versions of the order forms are available at <http://www.vdh.state.va.us/epidemiology/Immunization/VFC/vfcForms.htm>. Using the most current vaccine order form available on our website will help the Order Center correctly identify the vaccines you want in the package sizes available, and to more quickly and efficiently process your order. The revision date can be found in the lower right hand corner of the Order Form.

Vaccine orders can be mailed, faxed (804-864-8090), emailed (vvfc@vdh.virginia.gov), or phoned in (1-877-781-VVFC). During holiday periods, our order processing and delivery schedule may change. Usually vaccines are not shipped the week of Thanksgiving and the weeks of Christmas and New Year's Day.

When filling out the Order Form:

1. Fill out all of the information at the top of the order form including your **PIN** number
2. Let us know if any information has changed by circling the new information
3. Write in the number of doses on hand for each vaccine requested
4. Write in the number doses needed, keeping in mind that we cannot send partial packages (i.e. if the vaccine comes in a 5 dose vial you need to order 5, 10, 15, 20 doses etc)

VVFC will monitor requests and may adjust orders according to enrollment data and supply issues to equally distribute limited vaccine among providers and minimize loss of vaccine.

**When to Order Vaccines**

Due to the cost of shipping vaccine, ordering on a quarterly basis is strongly encouraged. If your storage unit is too small to accommodate a three-month supply of vaccine, contact your VVFC consultant. It is important to conduct a thorough vaccine inventory and order accordingly. Do not wait until you are almost out of vaccine before ordering. Re-order when you have about **two weeks** of inventory on hand. Do not order vaccine if your facility is going to be closed for a holiday or an extended vacation.

**Direct Ship Vaccines (Varicella & MMRV)**

The special shipping and storage conditions associated with direct-ship vaccines, Varicella and MMRV, require shipment directly from the manufacturer (Merck). They will arrive separately from the rest of your order on dry ice. Your facility should have procedures in place for immediate receipt and storage of these vaccines due to their temperature sensitivity.

**Missing or Incorrect Shipments**

If your vaccine does not arrive, call the VVFC Order Center so we can track your order.

If you receive an incomplete or inaccurate order, please contact the VVFC Order Center immediately. It is recommended that you keep your packing slips. Check the packing slip against your order to see if it is correct. You may be asked to check your stock by lot number to make sure you did not overlook receipt of the order.

**Vaccine Holds**

If your facility has been identified as having inadequate vaccine storage, excessive vaccine wastage, or other program violations, a temporary hold on vaccine ordering may be activated. The vaccine ordering hold will be lifted once the problem has been corrected.

# INVENTORY

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*Storage and Handling*  
*Temperatures*  
*Vaccine Stock Separation*  
*Accountability*  
*Rotating Stock*  
*Vaccine Returns*  
*Vaccine Replacements*  
*Vaccine Loss Due to Negligence*

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## **Storage and Handling**

It is important that all staff members recognize a vaccine delivery and know what to do upon its arrival. The shipment needs to be checked and stored in the refrigerator or freezer right away. Your facility should have procedures in place for immediate receipt and storage of vaccine due to its temperature sensitivity.

Separate refrigerator and freezer units are recommended for storing vaccine. Refrigerators or freezers used for vaccine storage must comply with the following requirements:

- Be able to maintain required vaccine storage temperatures year-round;
- Be large enough to hold the year's largest inventory;
- At a minimum, have a working certified thermometer inside each storage compartment;
- Be dedicated to the storage of vaccines.

Dormitory-style refrigerators are not adequate for storage of vaccines because they do not maintain appropriate temperatures. Dormitory style refrigerators are never acceptable for permanent storage of VFC vaccines. Storage units must be free of any food or drink. For additional information on vaccine storage and handling requirements, please refer to CDC's Vaccine Storage and Handling Toolkit available online at <http://www2a.cdc.gov/vaccines/ed/shtoolkit/>.

All staff should be familiar with your practice's written Emergency Response Plan for vaccine retrieval and storage in the event of a power outage or mechanical failure. Your Emergency Response Plan should be posted on or near your storage unit and updated on an annual basis.

## **Temperatures**

Keeping temperature logs of vaccine storage units to monitor viability of vaccines is required. Logging temperatures twice daily is mandatory to ensure appropriate temperatures are being maintained. Keeping temperature logs for a minimum of three years is required.

#### Troubleshooting Temperatures:

- Adjust the thermostat setting within the storage unit to obtain an adequate temperature and document action on your temperature log. Monitor for 24 hours.
- Test the existing thermometer by introducing a second thermometer.
- Check the placement of the thermometer. Vaccine should be stored in the center of the refrigerator. The thermometer should be kept as close to the vaccine stock as possible so the thermometer more accurately reflects the actual temperature of the vaccine. Areas of the refrigerator, such as the door or near the sides, may hold warmer temperatures than the center.
- Place water bottles in the refrigerator and ice packs in the freezer to help stabilize internal temperatures should power outages occur.
- Document each corrective action whenever temperatures are reported outside of the required range.

#### **Vaccine Stock Separation**

Public vaccine supplied through DOI must be stored separately from privately purchased vaccine. Clearly identify vaccine supplied by DOI at the time of receipt.

1. Establish procedures for vaccine receipt
  - Educate staff members about vaccine deliveries and the difference between stock supplied through DOI and private stocks.
  - Unpack vaccine in a timely manner and check the temperature indicator included with the shipment. Review the packing slip to verify it matches your order.
2. Keep copies of your public and private vaccine order forms and packing slips
3. Label vaccine supplied through DOI
4. Physically separate DOI and private stock
  - Use a dedicated refrigerator, or dedicated shelves or bins

#### **Accountability**

LHDs are required to submit quarterly inventories to the Division of Immunization. District accountability reports are created using these inventory and WebVision data. The quarterly reports are posted to the VDH internal website. Localities will be reminded of the dates for inventory reports.

FQHCs/RHCs, Public Hospitals, and large volume private providers are required to complete a monthly report which tracks doses administered and inventory. The report should indicate monthly doses administered of DOI provided vaccine to eligible children, and an ending inventory. Each monthly report is due by the fifth day of the following month. When the accountability report is run, it deducts doses administered, vaccine returns and waste, adjusts for transfers, and adds doses ordered within the span of the inventories you report. Providers who use the inventory module of the Virginia Immunization Information System (VIIS) can avoid sending these paper reports. For more information on using VIIS call the Division of Immunization at 800-586-1929.

Private providers who are not reporting monthly are required to complete a Tally Report tracking DOI supplied vaccine for a 2 month benchmark period. When completing the

report, be sure to record the refrigerator and freezer temperatures indicating Fahrenheit or Celsius. Record the number of *doses*, not vials, for each VVFC vaccine. Fax or mail the completed inventory to the Division of Immunization as indicated on the form. The VVFC Tally Report consists of initial and final inventories along with the doses administered data, vaccine shipments, returns and transfers during a specified time period. Providers will be notified in advance of the deadline for Tally Reports.

In order to improve accountability at your facility:

- Report all doses administered to eligible patients during the designated time period.
- List all DOI supplied vaccines in your inventory on the designated dates.
- Report all lost, spoiled, expired or wasted vaccine DOI supplied vaccine by completing a VVFC Return Form. Once wasted vaccine is reported do not count the doses in subsequent inventories even though you may still have them on hand after they are reported.
- Keep track of any vaccine that is administered to non-eligible patients on a VVFC Borrowing Form.
- Report transfers when they occur so that stock may be deducted from your inventory and added to the recipient's inventory.

### **Rotating Stock**

Organize your DOI supplied vaccine stock so doses with earlier expiration dates are used first. Upon receiving a shipment of vaccine, check expiration dates and store the earliest expiration dates in the front and the latest expiration dates in the back of the appropriate storage unit.

### **Vaccine Returns**

Please report any expired, spoiled, wasted, or transferred vaccine supplied through DOI by completing a VVFC Return Form. Report returns before or after taking a physical inventory, and once those doses are reported, do not include them in subsequent inventories even though you may still have them on-hand after they are reported. Once a return form is received, it will be deducted from your inventory on the date you indicate on the form. To reduce wastage, contact the Order Center to assist in transferring overstocked vaccine to a nearby provider. Please see <http://www.vdh.virginia.gov/Epidemiology/Immunization/VFC/documents/forms/Vaccine%20Return%20Process.pdf>.

### **Vaccine Replacement**

If your practice does not have DOI supplied vaccine in stock and an eligible child needs vaccinations, you may use vaccine from your private stock to immunize the child. Usage of your private stock vaccine should be documented on the Two Directional Borrowing Form. Once vaccine is received from DOI, you may administer corresponding number of doses to privately insured patients and document each dose on the VVFC Two Directional Borrowing Form. Instances of borrowing should be minimal. Please review <http://www.vdh.virginia.gov/Epidemiology/Immunization/VFC/documents/forms/Two-DirectionalBorrowing.pdf>

### **Vaccine Loss Due to Negligence**

The Division of Immunization will require providers to reimburse the VVFC Program for vaccine that has been wasted due to negligence or failing to correctly store, handle, or transport vaccine. Negligence is defined as loss of vaccine on the part of the provider/clinic staff. The following situations qualify in this category:

1. Vaccine stored improperly (i.e., refrigerating vaccine that should have been frozen, or freezing vaccine that should have been refrigerated)
2. Vaccine left out of refrigerator or freezer
3. Refrigerator or freezer unplugged or electrical service interrupted (circuit breaker)
4. Leaving the door of refrigerator or freezer ajar resulting in temperatures falling below the acceptable range
5. Prolonged storage of vaccines when temperatures are recorded out of range resulting in vaccine spoilage
6. Failure to properly read and record refrigerator(s) and freezer(s) temperatures, and/or failure to take immediate corrective actions when temperatures are out of appropriate range.
7. Pre-drawing or pre-mixing vaccine, then not administering in accordance with vaccine manufacturer/CDC recommendations
8. Transporting vaccine inappropriately (not using cool packs or dry ice), thus not maintaining the cold chain
9. Failure to notify VVFC Order Center when provider office hours change or the practice moves, resulting in vaccine spoilage
10. Discarding vaccine prior to the manufacturer's stated expiration date (e.g., discarding vaccine in a multi-dose vial 30 days after the vial is first used)
11. Expiration due to failure to notify the VVFC Order Center of need to transfer. Providers should notify the Order Center three months prior to expiration date of vaccine they cannot use to arrange for a vaccine transfer
12. Failure to rotate stock appropriately
13. Using dorm style refrigerators or using improper refrigeration unit to store the vaccine
14. Not using a certified thermometer and/or incorrect placement of the thermometer

***Note:** Temperatures recorded on temperature logs are considered official documents when making vaccine viability decisions. A thermometer's margin of error is not considered when temperatures are recorded at or below 35°F/2°C for refrigerators and at or above 6°F/15°C for freezers.*

Reimbursing the VVFC Program for wasted vaccine:

1. Instances of spoiled or expired vaccine supplied by DOI will be reviewed on a case-by-case basis. This review will help determine whether negligence was involved.
2. Excessive waste of vaccine may be determined to be abusive and will be evaluated in accordance to VFC Fraud and Abuse Policies.
3. If negligence is found and financial restitution is necessary, DOI will send the provider a letter informing the cost of the wasted vaccine.

# QA REVIEWS

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## *Quality Assurance (QA) Reviews*

### *Types of QA Reviews*

### *Recognition*

### *Frequency of QA Reviews*

### *Requesting Help*

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## **Quality Assurance (QA) Reviews**

Federal guidelines require Quality Assurance (QA) Reviews of each VVFC enrolled facility. The review evaluates your understanding of program compliance and includes vaccine storage checks. Reviews will be scheduled by phone two weeks prior to the desired visit date. After scheduling a QA Review, you will be sent a confirmation letter along with instructions on how to prepare for the visit. Reviews may occur any time. After the QA Review is completed, a summary letter including recommendations will be sent to you.

## **Types of QA Reviews**

Enrollment Visits (Member < 90 days): These visits are for newly enrolled providers in the VVFC program. The Consultant visits the provider and educates all appropriate staff members on VVFC program implementation. These site visits last approximately one hour. The consultant discusses VVFC program requirements and reviews 3 to 5 charts primarily to determine if the practice is already documenting appropriately. The consultant's findings are shared with the provider at the conclusion of the visit.

VFC Only Quality Assurance Visit: These are the most common type of visits that the VVFC Consultants perform. A VFC site visit is a formal visit to a VFC-enrolled provider site for the purpose of evaluating the provider's compliance with the VFC program requirements. This evaluation relies on the completion of the most current VFC Site Visit Questionnaire. These visits evaluate the following components of vaccine management:

1. Appropriate vaccine handling, storage and ordering procedures. This includes a physical inspection of vaccine storage units, temperature measuring devices, twice daily temperature recording, vaccine accountability, procedures for vaccine retrieval and storage in times of emergencies, and inventory management, including stock rotation to prevent outdating.
2. Proper documentation of children's eligibility status. This involves sampling a predetermined number of patient records (a mixture of active VVFC patients and privately insured patients) to ensure appropriate screening (e.g., Medicaid Uninsured, Alaska Native/American Indian, or Underinsured at a FQHC/RHC), and the administration of DOI supplied vaccines to eligible children.
3. Compliance with documentation and record retention requirements. This includes distribution of current Vaccine Information Statements and maintaining records in accordance with the National Childhood Vaccine Injury Act.



4. Compliance with other program requirements. This includes not charging for the cost of the vaccine, not charging a vaccine administration fee that is higher than the maximum fee established by the state, and agreeing not to deny vaccinations because of the parent's inability to pay a vaccine administration fee.

A VFC Quality Assurance Site Visit Summary Report is completed during this visit. This visit lasts approximately two hours. A QA summary letter is completed and mailed to the provider.

VFC and AFIX Quality Assurance Visit: A VFC/AFIX combined visit is a formal visit to a VVFC-enrolled provider site which integrates a VFC Only Visit (completion of the site visit questionnaire and vaccine management review to ensure compliance with the VFC program) with an immunization record assessment, followed by feedback guidance to help staff diagnose service delivery problems and adopt interventions for improvement, if necessary. VVFC consultants use a Clinic Assessment Software Application (CoCASA) developed by the Center for Disease Control and Prevention to provide an analysis of your facility's immunization rates. These visits require the facility to provide 50 charts of active patients for the immunization assessment (CoCASA). Due to the time it takes to enter the information into CoCASA, these site visits typically last between 3 to 6 hours. CoCASA reports are reviewed at the end of these visits as well as mailed to the provider along with the QA report summary letter.

AFIX Only Visit: An AFIX site visit is a formal visit to a private or public provider site to perform quality improvement activities. These visits consist of performing either a childhood or adolescent immunization rate assessment during the visit. These visits are usually performed on facilities that have recently received a VFC Only Quality Assurance Visit (< 6 months) or by special request. CoCASA reports are reviewed at the end of these visits as well as mailed to the provider along with a summary letter.

Qualitative AFIX Visit: An AFIX Qualitative visit is defined as an AFIX visit in which all components were implemented but during the assessment portion coverage levels were not generated because of the small number of patients in the designated age range for the assessment. These visits can be performed alone or as a part of a VFC and AFIX combined visit. This type of visit is usually performed on a facility if they have less than 10 active patients in the specified age range (childhood or adolescent). The immunization histories will not be entered into CoCASA. The consultant will review the charts and ensure vaccines are being administered according to the ACIP schedule and will also check for proper chart documentation.

Educational Visit: While all site visits are designed to be educational, these visits are completed for groups who wish to learn more about childhood immunizations or the VVFC program in general. Many times these visits are performed for individuals or facilities that are not members of VVFC or staff that are not in direct contact with the VVFC program. In general these visits are used to increase knowledge and understanding on vaccine handling and storage and the VVFC program. These visits are tailored to fit the groups' individual needs/requests and vary in duration.

Storage Check Visit: This is a visit where storage temperatures/conditions are checked. Due to the variation of conditions, these visits have no set time. A Storage Check visit is considered a VFC site visit follow-up (see below).

VFC Site Visit Follow-up: A VFC site visit follow-up is defined as any contact made with a VFC-enrolled provider to review progress towards correcting a problem identified during the most recent VFC site visit.

### **Recognition**

Providers exhibiting outstanding program compliance or exceptional immunization rates are recognized in VVFC's newsletter, the *Backpage*. In order to receive recognition and a VVFC Gold Star Award Certificate for outstanding program compliance, a practice must have appropriately answered every high priority question on the VFC questionnaire.

Providers participating in an AFIX visit who achieve a childhood immunization rate of 92% or above or an adolescent immunization rate of 90% or above are also recognized and receive with a VVFC Gold Star Award Certificate.

Providers are also recognized for implementing process improvements at their facilities that improve quality of care. A VVFC Gold Star is awarded in addition to the process improvement being highlighted in the *Backpage* newsletter.

Each quarter, VVFC also recognizes an "Immunization Champion." An Immunization Champion is a VVFC provider who has distinguished itself in an outstanding way. The Immunization Champion is highlighted in the *Backpage* newsletter and spotlighted on our website. Immunization Champions may be contacted in an advisory capacity when VVFC is considering programmatic changes or when feedback is sought on an existing policy or procedure.

### **Frequency of QA Reviews**

QA Reviews are generally performed at each VVFC facility annually. Consultants may schedule additional reviews if they feel they are warranted.

### **Requesting Help**

VVFC staff is available to help you. A provider can request assistance, educational materials, or guidance from the Division of Immunization. To make a request, contact your regional consultant or the Central Office at (800) 568-1929.

# ADDITIONAL RESOURCES

Please visit the following web addresses for additional or supplemental information related to the Virginia Vaccines for Children program.

VVFC Home Page:

<http://www.vdh.virginia.gov/Epidemiology/Immunization/VFC/index.htm>

VFC Home Page: <http://www.cdc.gov/vaccines/programs/vfc/index.html>

VVFC Resource Numbers:

[http://www.vdh.virginia.gov/Epidemiology/Immunization/VFC/documents/resource\\_numbers.pdf](http://www.vdh.virginia.gov/Epidemiology/Immunization/VFC/documents/resource_numbers.pdf)

Recommended Childhood and Adolescent Immunization Schedules:

<http://www.cdc.gov/vaccines/schedules/index.html>

CDC Recommended Vaccine & Immunization Guidelines:

<http://www.cdc.gov/vaccines/recs/default.htm>

Additional VVFC forms:

<http://www.vdh.virginia.gov/Epidemiology/Immunization/VFC/vfcForms.htm>

Vaccine Adverse Event Reporting: <http://vaers.hhs.gov/professionals/index>

Contraindications For Childhood Immunizations: <http://www.cdc.gov/vaccines/recs/vac-admin/contraindications-vacc.htm>

Reportable Diseases in Virginia:

<http://www.vdh.virginia.gov/epidemiology/immunization/surveillance.htm>

Epidemiology and prevention of Vaccine Preventable Diseases (The Pink Book):

<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

The ACIP-VFC Vaccine Resolutions:

<http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html>

National Immunization Survey Data: <http://www.cdc.gov/vaccines/stats-survey/nis/default.htm>

Information on FAMIS and FAMIS Plus: <http://www.famis.org/faq.cfm?lang=English>